JUN 2 0 2013

5. 510(K) SUMMARY

Submitter's Name:	Spinal USA
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	601-420-4244
Authorized Contact Name:	Meredith May, Authorized Contact Person
Contact's Telephone:	719-337-7579
Date Summary was Prepared:	04-Feb-13
Trade or Proprietary Name:	ReForm Pedicle Screw System
Common or Usual Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Spondylolisthesis Spinal Fixation Orthosis , Spinal Interlaminal Fixation
Classification:	Class II per 21 CFR §888.3070 and §888.3050
Product Codes:	MNI MNH KWP
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	PSS System (ReForm Pedicle Screw System), K121172, K092128, K090033, K073240, K071438 Biomet 5.5 Polaris Spinal System K091067

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Reform System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, locking cap screws, hooks, domino connectors, and lateral offset connectors. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are made from medical grade stainless steel, cobalt chromium alloys, titanium or titanium alloy described by such standards as ASTM F138, ASTM F1537, ISO 5832-12, ASTM F136 or ISO 5832-3.

CHANGE FROM PREDICATE:

The purpose of this submission is to make modifications/additions to the components of the PSS System (ReForm Pedicle Screw System) cleared in K121172, K092128, K090033, K073240, and K071438. The standard construct is modified by the addition of hooks and rod to rod connectors.

TECHNOLOGICAL CHARACTERISTICS:

The intended use and technological features of the modifications/additions to the components of the PSS System (ReForm Pedicle Screw System) do not substantially differ from the legally marketed predicate devices, which are the PSS System (ReForm Pedicle Screw System, K121172, K092128, K090033, K073240, and K071438) and the Biomet 5.5 Polaris Spinal System (K091067). The predicate devices and the subject additions to the PSS (ReForm) system are designed for posterior stabilization to provide immobilization and stabilization of spinal segments as an adjunct to fusion.

INDICATIONS FOR USE

The ReForm Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The ReForm Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3and 4of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis) spinal tumor; pseudloarthrosis; and failed previous fusion.

PERFORMANCE DATA

The ReForm Pedicle Screw System was tested in dynamic axial compression per ASTM F1717-12 and proved to not create a new worst-case construct.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that ReForm Pedicle Screw System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

Spinal USA
% Empirical Testing Corporation
Ms. Meredith May
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K130279
Trade/Device Name: ReForm Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: February 4, 2013
Received: May 7, 2013

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: ReForm Pedicle Screw System

The ReForm Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130279